Potential Human Health Data to Support an Experimental Use Permit for OX513A Mosquitoes

Biochemical data requirements (40 CFR 158.2083) are appropriate for OX513A mosquitoes.

Tier I Biochemical data requirements

Data Requirement	OCSPP Guideline	Data/Information to Meet
		Requirement
Acute Testing		
Acute oral toxicity - rat	870.1100	Rationale supported with data
Acute dermal toxicity	870.1200	Rationale supported with data
Acute inhalation toxicity - rat	870.1300	Rationale supported with data
Primary eye irritation - rabbit	870.2400	Rationale supported with data
Primary dermal irritation	870.2500	Rationale supported with data
Hypersensitivity incidents	none	
Subchronic Testing		
90-day oral (one species)	870.3100	Rationale supported with data
Developmental Toxicity		
Prenatal developmental - rat preferably	870.3700	Rationale supported with data
Mutagenicity Testing		
Bacterial reverse mutation test	870.5100	Rationale supported with data
<i>In vivo</i> mammalian cell assay	870.5300	Rationale supported with data

Rationale supported with some additional data may be used to develop multiple lines of evidence supporting conclusions of no reasonable expectation of adverse effects to humans. Such data include bioinformatics for tTAV and dsRED and evidence of a lack of detectable tTAV and dsRED in mosquito saliva.